CORRIGENDUM NOTICE

Ref No.: AIIMS/NGP/ANAT/CATCH TRIAL/25-26/01 **Dated:** 22/08/2025

Subject: Extension of Submission Deadline – NIQ for Clinical Trials Liability Insurance for the ICMR-AYUSH funded CATCH Trial

With reference to the Notice Inviting Quotation (NIQ) titled "Clinical Trials Liability Insurance for the ICMR-AYUSH funded CATCH Trial", issued under reference number **AIIMS/NGP/ANAT/CATCH TRIAL/25-26/01** dated **22/08/2025**, the submission deadline is hereby extended. The original deadline of **29/08/2025** is now revised to **10/09/2025**.

All other terms and conditions of the NIQ shall remain unchanged. Interested vendors are requested to take note of the revised date of submission of NIQ and submit their quotations accordingly.

04/9/2025

Administrative Officer
AIIMS Nagpur

शब्बीर शेख / Shabbir Sheikh
प्रशासनिक अधिकारी/Administrative Officer
अ.भा.आ.सं. नागपुर/AIIMS Nagpur

अखिल भारतीय आयुर्विज्ञान संस्थान नागपुर
ALL INDIA INSTITUTE OF MEDICAL SCIENCES, NAGPUR
Address: Plot no.2, Sector -20, MIHAN, Nagpur - 441108
Website: www.aiimsnagpur.edu.in
DEPARTMENT OF ANATOMY

NIQ No. AIIMS/NGP/ANAT/CATCH TRIAL/25-26/01 **DATE: 22/08/2025**

NOTICE INVITING QUOTATIONS

The Executive Director, All India Institute of Medical Science Nagpur invites quotations from interested Indian insurance agencies or IRDA approved intermediaries (Agents/brokers/Corporate agents/Insurance companies etc.) for providing a Clinical Trials Liability Insurance coverage for patients participating in the ICMR-AYUSH funded CATCH trial. Please mention the details as follows: -

Particular	Limit of liability for death claim, per subject and in aggregate	Deductible for death claim	Medical expense per subject and in aggregate	Deductible for medical expense	Annual Premium with GST for first year	Annual Premium with GST for second year	Annual Premium with GST for third year	Additional charges per subject with GST, if any
Clinical Trials Liability Insurance Coverage- CATCH Trial								
Extended Reporting period								
Extensions								

In accordance with regulatory and ethical requirements (as per ICMR and GCP guidelines), we seek to secure insurance coverage for all enrolled participants to cover risk safety against any trial-related injury or serious adverse event (SAE). The technical specifications for the same are mentioned in Annexure I.

Clinical trial insurance for the following is required:

Compensation for 'Trial related injuries' for study participants as per 'New Drugs and Clinical Trials Rules, 2019, [G.S.R. 227(E)] dated 19 March 2019' and medical management for adverse events related to study intervention and not natural disease progression.

The interested insurance companies or agencies on behalf of insurance companies should prescribe the conditions and extent of coverage, date of commencement and expiry of coverage thereof, including the premium and other costs, as per rules for the aforementioned study.

TERMS OF CONDITIONS:

1. All quotations to be submitted in the name of Executive Director, AIIMS Nagpur only. Quotations not addressed to Executive Director, AIIMS, Nagpur will not be opened and rejected summarily.
2. Copy of NIQ along with annexure duly signed and stamped by the vendor to be submitted

along with quotation by accepting all the terms and condition of the NIQ.

3. Vendors are requested to submit detailed technical specification of quote along with brochure approved with IRDA, if available.
4. Quotation without technical specification will be strictly rejected
5. Premium amount to be quoted annually along with GST for 3 years separately.
6. Premium amount will be paid on annual basis.
7. Bank details such as Account Number, IFSC Code etc. should be furnished so as to facilitate payment of premium on acceptance of quote and release of work order.
8. A declaration by vendor is required to be submitted along with quotation station that vendor is not debarred by Department of Commerce or Ministry/ Department concerned. The date of declaration should not be before the date of NIQ and after the last date of submission of quotation.
9. The Agency should be able to have a qualified medical practitioner (minimum MBBS) to coordinate with the clinical team for any insurance support.
10. Rights to accept/reject any quotation rests with the AIIMS Nagpur.

Please email the quotation with complete documentation to gayatrimuthiyan@aiimsnagpur.edu.in. Please email on the above-mentioned email address if you need any further clarification.

Please submit the hard copy of the quotations in sealed envelope to following address: **"Store office, Admin block, AIIMS Nagpur, MIHAN, Plot No 2 Sector 20 MIHAN Nagpur.", super scribing: - "Quotation for Clinical Trials Liability Insurance Coverage- CATCH Trial, Department of Anatomy, AIIMS Nagpur" w.r.t. NIQ No. AIIMS/NGP/ANAT/CATCH TRIAL/25-26/01, dated: 21/08/2025" on or before 29/08/2025 before 17.00hrs, which will be opened on 30/08/2025 at 11.00 hrs.**

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Additional Professor, Dept. of Anatomy,
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Annexure I

Technical Specifications of policy

The All India Institute of Medical Sciences (AIIMS) Nagpur is conducting the academic clinical trial funded by Indian Council of Medical research entitled "*Efficacy of Comprehensive Ayurvedic Treatment (CAT) as Add-On to Conventional Bio-Medicine in Improving the Quality of Life (Qol) in Unresectable Stage III – IVB Head-Neck Squamous Cell Carcinoma (HNSCC) Patients: An Assessor Blind Randomized Controlled Trial, CATCH Trial.*"

This randomized controlled clinical trial is being conducted under the approval and oversight of the Institutional Ethics Committee (IEC) and is registered with the Clinical Trials Registry of India (CTRI). The trial involves the recruitment of 100 adult participants (50 in each arm i.e. intervention and control arms) diagnosed with Unresectable Stage III – IVB Head and Neck Squamous cell carcinoma (HNSCC). The participants will be recruited after a comprehensive screening process as per inclusion and exclusion criteria: involving haematological, radiographic etc. assessments for final inclusion and staging. The control arm will receive standard treatment with Concomitant Chemoradiotherapy (CRT) with modern volumetric arc modulated radiotherapy (VMAT) and trial/intervention arm will receive Comprehensive Ayurveda Treatment (CAT) as add-on to standard treatment. Regular evaluations by clinicians and Ayurvedic experts will occur periodically, including physical examinations and relevant investigations (radiological, cytokines, epigenetic markers etc.) to monitor treatment progress, outcomes (QoL, Psychological distress, safety and efficacy). Each participant will be followed up for 6 months and total duration of the study is 3 years.
The start date for the project as per CTRI registration is 16.08.2025. However, patient recruitment will commence only after the trial insurance policy is obtained.

Sr. No.	Item	Specifications
1)	Phase of trial and sponsor	Phase II Academic Clinical trial sponsored by Indian Council of Medical Research (ICMR), New Delhi
2)	Site of the trial	AIIMS Nagpur
3)	Sample size	100 (50 in each intervention and control arm). *Tentatively 40 subjects will be recruited in first year of the study, 40 in second year and 20 in third year. However, the numbers are liable to change based on the actual footfall of the patients.
4)	Minimum limit of liability	1 Crore per subject and in aggregate annually. AOA:AOY = 1:1
5)	Medical Expense	2.5 lakh / 5 lakh per subject and 15 lakh/ 25 lakh in aggregate annually
6)	Reporting period for submitting claims	1. Reporting period for submitting claim for compensation for death or SAE other than death will ordinarily be in the 12-month annual policy period, within which the SAE or death occurred, irrespective of the date of enrolment of the subject. 2. Reporting period for submitting claim for legal costs will ordinarily be in

		the 12-month annual policy period, within which the legal cost was incurred, irrespective of the date of enrolment of the subject.
7)	Extended reporting period:	To account for death, SAE or legal costs incurred towards the end of a 12-month annual policy period, an extended reporting period of 6 months must be provided after the end of each annual policy period during which time a claim of death, SAE or legal costs can be notified.
8)	Deductibles:	1. Deductible per claim will not exceed INR 10,000 2. Aggregate upper limit of the deductibles of all claims will be capped at INR 1 lakh per annum or less 3. The aggregate upper limit on the deductibles will be irrespective of the number of patients for whom claims are submitted and irrespective of the amount claimed within the limits of the AOY, AOA and per-patient sub-limit
9)	Authority that will decide whether death or SAE is related to participation in the clinical trial	1. Whether an enrolled patient's SAE or death is related to the clinical trial will solely be determined by the Data Safety Monitoring Committee and Institutional Ethics Committee 2. The vendor will have no authority to decide on matters of relationship of the SAE or death to the trial
10)	Renewal of insurance cover	1. Insurance cover will be renewed on an annual basis for 3 years or more if trail extended. But assured renewal for 3 yrs is must at same terms and conditions. 2. The Insurance company/Vendor will not refuse renewal on account of claims if any in the preceding year
11)	Legal liability coverage	1. Vendor will provide Professional Indemnification for all the Investigators, physicians, nurses, research staff and the trial site 2. Vendor will provide legal liability cover for all the research investigators, the sponsor (ICMR and CCRAS New Delhi), institutional ethics committee members, all research staff employed under the project, subject to the below mentioned points: a) The policy will cover the costs resulting due to legal cases arising from the conduct of the study. b) The coverage will be extended to include negligent act, error or omission of the insured in rendering or failure to render medical professional services to the enrolled patient during the period that the patient was in the clinical trial, which result in or may result in the adverse event or death of the patient. c) Legal defense costs will be included within the per patient sub-limit of liability, ie. the sub-limit will include both the compensation to patients for death or SAE as well as legal defense costs. d) Time limit for submitting claim for legal defense costs: any time within the 12-month policy period that the legal defense cost was incurred, irrespective of the time period when the concerned patient actually suffered a SAE or death plus the extended reporting period

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Protocol Summary

This is an assessor-blind, open-label, parallel-group randomized controlled trial being conducted at AIIMS Nagpur, with approval from the Institutional Ethics Committee and registration under the Clinical Trials Registry of India. The study will recruit 100 adult participants diagnosed with unresectable Stage III–IVB head and neck squamous cell carcinoma (HNSCC), with 50 participants in each arm. Eligibility will be determined through a comprehensive screening process, including hematological tests, imaging, and other relevant assessments to confirm diagnosis and staging.

Participants in the control arm will receive standard treatment with concurrent chemoradiotherapy (CRT) using modern volumetric modulated arc therapy (VMAT). Those in the intervention arm will receive the same CRT along with a Comprehensive Ayurveda Treatment (CAT) package. This includes Ayurvedic procedures such as Nasya, Kawal (therapeutic gargling), and Matra Basti cycles administered on a day-care basis, in addition to oral Ayurvedic medicines and personalized dietary and lifestyle guidance. Treatment adherence will be monitored throughout the study.

All participants will be assessed using structured questionnaires to gather information on socio-demographic and behavioral characteristics, clinical details, genetic markers, quality of life, and pain status. Standardized tools including the EORTC QLQ-H&N35, FACT-H&N, Beck Depression Inventory (BDI), and Visual Analogue Scale (VAS) will be administered at baseline, 3 months, and 6 months. Regular clinical evaluations will be conducted by oncologists and Ayurvedic specialists, supported by relevant investigations such as radiological imaging and biomarker assessments (cytokines, epigenetic markers) to monitor treatment progress, outcomes (QoL, Psychological distress, safety and efficacy). Each participant will be followed for 6 months, with the overall study duration planned for 3 years.